A randomized controlled trial of clean intermittent self-catheterization versus suprapubic catheterization after urogynecologic surgery

Mary L. Jannelli, MD; Jennifer M. Wu, MD; Linda W. Plunkett, MSN; Kathryn S. Williams, BS; Anthony G. Visco, MD

OBJECTIVE: The purpose of this study was to compare the risk of significant bacteruria between clean intermittent self-catheterization (CISC) and suprapubic catheterization (SPC) after urogynecologic surgery.

STUDY DESIGN: Patients were randomized to CISC or SPC. A urinalysis and patient satisfaction questionnaire were conducted on postoperative days 2 and 7. Urine culture was performed for positive urinalysis. Significant bacteruria was defined as $>$ 100,000 cfu/mL. To detect a decrease in bacteruria risk from 25% to 10%, 113 subjects per group were needed with 80% power and α of 0.05.

RESULTS: Of 248 randomized patients, 210 were included in the final analysis. The overall risk of bacteruria was 27% with no difference between SPC and CISC (31% vs 23%, $P = .23$). Patients reported more frustration ($P = .01$) and more difficulty ($P = .003$) using CISC.

CONCLUSION: There was no difference in risk of significant bacteruria between CISC and SPC. Patients reported more frustration and difficulty with self-catheterization.

Key words: clean intermittent self-catheterization, postoperative bladder drainage, significant bacteruria, suprapubic catheterization

Cite this article as: Jannelli ML, Wu JM, Plunkett LW, et al. A randomized controlled trial of clean intermittent self-catheterization versus suprapubic catheterization after urogynecologic surgery. Am J Obstet Gynecol 2007;197;72.e1-72.e4.

Bladder drainage is common practice after surgery for urinary incontinence and pelvic organ prolapse. In the postoperative period, approximately 2.5% to 33% of patients may experience temporary voiding difficulties requiring bladder drainage.[1-3] Voiding dysfunction after surgery may be due to hyperelevation of the bladder neck or narrowing of the urethra.[4] Other etiologies include edema of the retropubic space, inflammation at the bladder neck, and pain from the surgical incision site.[5]

Bladder drainage can be achieved by indwelling transurethral catheterization, suprapubic catheterization (SPC), and clean intermittent self-catheterization (CISC). Catheter choice is often based on surgeon experience and preference. A recent Cochrane review of urinary catheter policies for short-term bladder drainage concluded that suprapubic catheters are associated with less bacteruria and patient discomfort than indwelling catheters.[6] CISC is an alternative method to drain the bladder. Advantages include a lower risk of bacteruria than indwelling transurethral catheterization.[7] This method has been shown to have good patient acceptance and allow for a good quality of life in patients that require long-term catheterization.[8-10] There are limited data comparing SPC to CISC. One small study by Naik et al randomized 40 women to CISC or SPC following radical hysterectomy. They found a higher rate of bacteruria in the CISC group; however, patients were more likely to prefer this method of bladder drainage.[11]

Therefore, we conducted a randomized clinical trial to compare the rates of significant bacteruria with suprapubic catheterization to clean intermittent self-catheterization in patients who have undergone urogynecologic surgery. Secondary objectives were to assess patient satisfaction, comfort, and days until return to spontaneous voiding.

Materials and Methods

After Institutional Review Board approval was obtained, all eligible women scheduled for surgery for stress urinary incontinence or anterior vaginal wall prolapse at the University of North Carolina at Chapel Hill were recruited from November 2000 to April 2005. Women were ineligible if they had preoperative bacteruria, urinary retention, voiding dysfunction, or history of urethral trauma. The research nurse obtained informed consent at the preoperative visit. All patients were then instructed on how to perform self-catheterization and, if unable, they were excluded.

A research nurse revealed randomization assignment to CISC or SPC on the day of surgery. Assignments were kept in sealed, sequentially numbered, opaque envelopes and were generated using a computer generated random number table in blocks of 4. The block length was not revealed. At the time of surgery, masking of the physician or patient to the assignment was not feasible given the nature of the intervention. Women ran-

From the Department of Obstetrics and Gynecology, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC.

Presented at the 27th Annual Scientific Meeting of the American Urogynecologic Society, Oct. 19-21, 2006, Palm Springs, CA.

Received July 15, 2006; revised Jan. 4, 2007; accepted Feb. 27, 2007.

Reprints not available from the authors.

0002-9378/$32.00

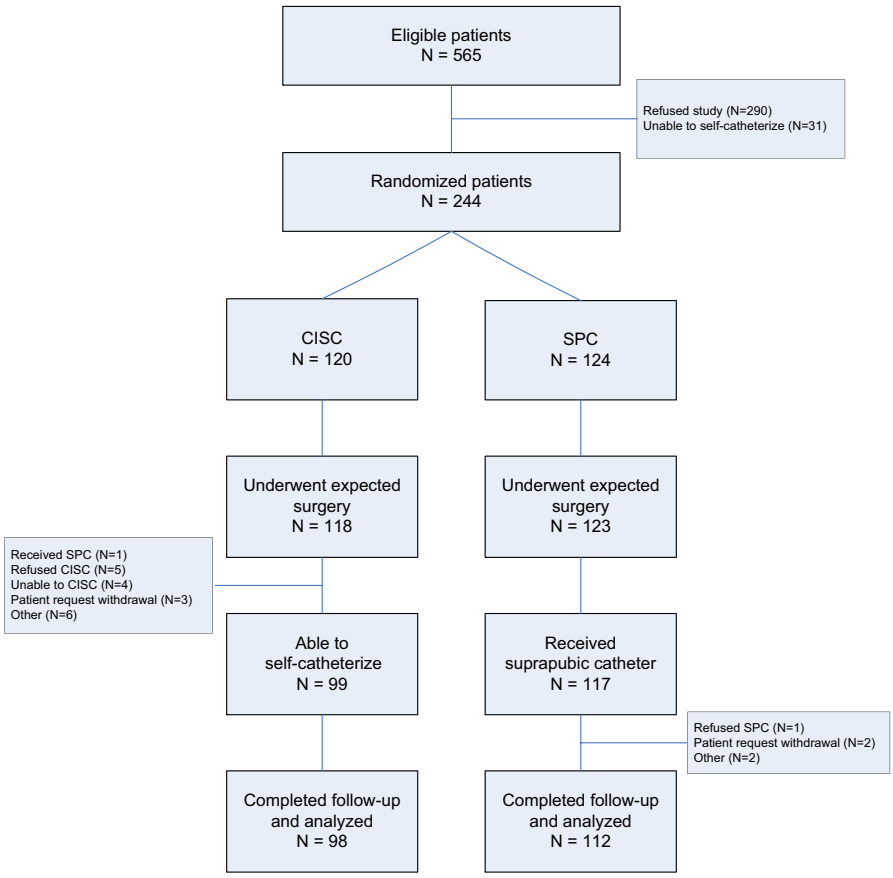
doi: 10.1016/j.ajog.2007.02.043

domized to CISC had a 16 French silicone Foley catheter placed intraoperatively to allow for monitoring of urine output in the immediate postoperative period. The Foley catheter was removed in the morning of postoperative day 1, after which the patient began to self-catheterize. Fourteen French disposable vinyl catheters (Mentor, Minneapolis, Minn) were used for CISC. Women randomized to the SPC group had a Bonanno suprapubic catheter (Becton Dickenson, Franklin Lakes, NJ) placed intraoperatively. All patients received appropriate preoperative antibiotic prophylaxis.

A urinalysis was performed on postoperative days 2 and 7. Urine was sent for culture and sensitivity if leukocyte esterase or nitrites were present. Any positive urine culture was treated with appropriate antibiotics. The primary outcome was significant bacteruria defined as greater than 100,000 colony-forming units/milliliter (cfu/mL) on urine culture from either postoperative day 2 or 7. The secondary outcome was patient satisfaction, which was assessed by a visual analog scale questionnaire administered on postoperative days 2 and 7. Patients were asked to put an "X" on a 10-cm line between the 2 extremes. The distance from the beginning of the line to the patient's X was measured and the score was obtained.[12,13] Overall pain, pain from the catheter, ease of catheter use, degree of frustration with drainage method, limitations in social activities, and interest in using method again were evaluated. Data were also obtained on the number of days until return to adequate voiding, which was defined as a postvoid residual (PVR) $<$ 100 mL or less than 30% of voided volume on 2 consecutive voids. Patient demographics, stage of prolapse, surgical procedures performed, and catheter complications were also recorded.

A sample size of 113 patients per group was needed in order to detect a decrease in significant bacteruria rate from 25% to 10% with 80% power and α equal to 0.05.[14,15] We planned to recruit about 250 patients to allow for a 10% attrition rate. Statistical analysis was performed with STATA 9.0 (Stata Corporation, College Station, Tex). All comparisons between groups were based on intention-to-treat. Comparisons between groups were made with χ^2, Student t test, and Wilcoxon rank sum test as appropriate. Statistical significance was defined as $P < .05$.

FIGURE
Flow diagram of randomized trial of clean intermittent self-catherization (CISC) to suprapubic catherization (SPC) in women after urogynecologic surgery



Results

Of 565 eligible women, 244 were enrolled and randomized, 290 declined to participate and 31 were unable to self-catheterize (Figure). After randomization, 3 women did not undergo the expected surgery, 2 in the CISC group and 1 in the SPC group. For the CISC group, 1 subject received a suprapubic catheter. Of the 99 subjects able to self-catheterize, 98 completed follow-up and were analyzed. For the SPC group, 117 received a suprapubic catheter and 112 completed follow-up and were analyzed. There were no significant differences in demographics, body mass index, stage of prolapse, or operative procedures between the patients who were excluded and those who were analyzed.

Demographic and physical examination findings for study women are shown in Table 1. The CISC and SPC groups were similar in age, race, parity, and body mass index. The preoperative stage of prolapse, based on the pelvic organ prolapse quantification (POP-Q) examination, was similar between groups. There were also no differences in the operative procedures performed (Table 2). As the type of surgical incision might impact the ability to self-catheterize, the proportion of subjects with an abdominal or vaginal incision was compared; there was no difference between the CISC and SPC groups.